REMARKS

Status of the Claims

Claims 1, 7, 14-17, 26, 30, 33, 45, 61, 65, 68, and 74-87 are pending. Claims 2, 31, and 83 are cancelled. Claims 86 through 89 are new. Claims 1, 30, 61, and 84 are currently amended.

Support for the Amendment

Claims 1, 30, and 61 are amended to reflect that the second electrode includes the metal complex mediator and does not include other mediators that would materially affect the basic electrochemical operation of the second electrode. This strip electrode construction may be found, for example, in Example 2. Claim 84 is amended to bring the language better in accord with the amendment made to claim 61. New claims 88 and 89 rely on the language of claim 84, but depend from independent claim 1 and 30, respectively.

Support for new claims 86 and 87 may be found in the first paragraph of page 5 and in the third paragraph of page 6, for example, of the underlying PCT application. These and other paragraphs of the application define a redox pair as the reducible and oxidizable forms of the same molecule. The second soluble redox species of the redox pair is capable of undergoing the opposite electrochemical reaction of the first soluble redox species of the redox pair. Thus, no new matter has been added.

Interview Summary:

The Applicants would like to thank the Examiners for the helpful discussions with Applicants' representative on May 2, 2011. During this discussion, the pending claims were reviewed in relation to the art of record. Applicants' representative and the Examiners agreed on the direction of claim amendments to address the Examiners' concerns. Agreement was reached regarding the withdrawal of the rejection of claim 85 under § 112.

The Art of Record:

D1: US Patent 6,287,451 to Winarta:

D1 teaches a sensor strip having working and counter electrodes made from the same reagent composition, except that the counter electrode lacks an enzyme. Col. 8, Lines 37-47. Thus, the enzyme is present only at the working electrode. The same oxidized form of a single redox mediator (potassium ferricyanide) is used in the reagent composition for both electrodes ("Reagents 1 and 2 comprise the oxidized form of a redox mediator..."). Col. 9, Lines 15-19. This formulation also is described in Col. 10, Lines 44-46 and Lines 53-56, where only potassium ferricyanide is included in the reagent compositions. Thus, D1 teaches that the oxidized (thus reducible) redox species (potassium ferricyanide) of a single metal complex mediator is present at both the working and counter electrodes, and that an enzyme is present at the working electrode, but not at the counter electrode.

D2: US Pub. 2001/0006149 to Taniike:

D2 teaches sensor strips where the enzyme is present at the working, but not at the counter electrode, and where the oxidized form (ferricyanide) of a single redox mediator is present at the counter, but not at the working electrode. Para. [0050]. D2 also teaches that metal complexes and electroactive organic molecules are mediators and that mediators may be used singly or in combinations of two or more. Para. [0036]. Furthermore, each of the examples in the patent describe sensor strips where an enzyme, but no mediator, is deposited at the working electrode, while a mediator, but no enzyme is deposited at the counter electrode.[1] Thus, D2 teaches the superiority of a sensor strip having only enzyme at the working electrode and ferricyanide at the

[1] A "comparative example" having the same enzyme and ferricyanide soluble redox species of a metal complex mediator at both the working and counter electrodes was prepared as a prior art device to which the Example strips were compared. Para. [0046]-[0048].

counter electrode in relation to a strip having enzyme and ferricyanide at both the working and counter electrodes. Para. [0049]-[0051].

D9: US Pub. 2001/0052470 to Hodges:

In Para. [0009] D9 teaches a reagent composition including an enzyme and a mediator, where excess mediator is required to allow the enzyme to function catalytically. D9 continues to teach that "Ideally there is initially no ferrocyanide, although in practice there is often a small quantity." In Para. [0070] D9 teaches that this composition may be deposited onto the palladium surface, and that this enzyme/ferricyanide with a trace of ferrocyanide mediator composition may be deposited on one electrode while a buffer is deposited at the other electrode. Thus, D9 teaches circumstances where the same enzyme/metal complex mediator is deposited at the working and possibly the counter electrode, or the circumstance where the enzyme/metal complex mediator is deposited at the working electrode while a buffer is deposited at the counter electrode.

Request for Reconsideration

Summary of Claimed Subject Matter

Applicants' independent device claims are directed to sensor strips specifying an organic mediator at a first electrode and both redox species of a metal complex mediator at a second electrode. Applicant's independent method claim uses a sensor strip having an organic mediator at a first electrode and a metal complex mediator at a second electrode where a substantially linear correlation between current and analyte concentration is obtained from zero to about 400 mg/dL. As amended, the claims specify that the second electrode consists essentially of a redox pair selected from the group consisting of an organotransition metal complex, a transition metal coordination complex, and mixtures thereof.

In view of the Interview of May 2, 2011, Applicants believe that the Examiner's concerns under 103(a) have been overcome through amendment. Independent claim 1

now specifies that the second electrode consists essentially of a redox pair selected from the group consisting of an organotransition metal complex, a transition metal coordination complex and mixtures thereof. As the first electrode includes an organic mediator, and the second electrode includes a metal complex mediator while excluding other mediators that would materially affect the basic electrochemical operation of the second electrode, the claims as amended are believed patentable.

The Claims are Not Anticipated by or Obvious Over the Cited Art

Applicants note that the prior rejections under 35 U.S.C. § 102 have been overcome.

The rejection under 35 U.S.C. 103(a) of claims 1, 2, 4, 14, 15, 16, 17, 23, 26, 30, 31, 45 and 74-80 as being obvious over U.S. Pat. No.6,287,451 (D1) ("*Winarta*") in view of U.S. Pat. Pub. No. 2001/0052470 ("Hodges") (D9) and U.S. Pat. Pub. No. 2001/0006149 ("*Taniike*") (D2) is believed to have been rendered moot by appropriate amendment.

As amended, Applicants' claim 1 specifies that a first electrode includes an electroactive organic molecule and an oxidoreductase, and that a second electrode includes both species of a soluble redox pair of a metal complex mediator in a range of ratios while excluding other mediators that would materially affect the basic electrochemical operation of the second electrode. None of the cited references, alone or in combination, teach or in any way suggest that an organic mediator should or could be successfully used on a first electrode, while a metal complex mediator is used on a second electrode of the same sensor strip. The cited references also fail to teach that a ratio of the reduced and oxidized forms of the metal complex mediator should be used at the second electrode. Neither can D2's general teaching to the possible substitution or mixture of a metal complex mediator with an organic mediator make obvious the separate use of these different types of mediators at the first and second electrodes of the same sensor strip.

Absent a teaching from the references to pick different mediator types and deposit them separately on different electrodes of the same sensor strip, such a construction cannot be obvious as there is no motivation or suggestion to try such. As more fully described in Applicants' prior response, the general teaching of D2 to the possible substitution of a metal complex mediator with an organic mediator provides no teaching or motivation to segregate two different types of mediators on different electrodes of the same strip, and in fact, teaches away from separately using both.

For the reasons above, the limitations of claim 1 cannot be obvious in view of D1, D9, and/or D2. The arguments made with regard to claim 1 apply equally to independent claim 30, as claim 30 also specifies the organic and metal complex mediators at the first and second electrodes, respectively. As the claims depending directly or indirectly from claim 1 or 30 include the limitations of claim 1 or 30, these dependent claims also are not obvious in view of D1, D9, and/or D2. Applicants' respectfully request that the rejections under 35 U.S.C. § 103(a) of independent claims 1 and 30 and their respective dependent claims be withdrawn.

The rejection under 35 U.S.C. 103(a) of claims 61, 65, 68, and 81-85 as being obvious over U.S. Pat. No.6,287,451 (D1) ("*Winarta*") in view of U.S. Pat. Pub. No. 2001/0006149 ("*Taniike*") (D2) is respectfully traversed.

Method claim 61 specifies a method where the correlation between the current and the concentration of the analyte is substantially linear from zero to an analyte concentration of about 400 mg/dL for a sensor strip using an organic mediator at a first electrode and a metal complex mediator at a second electrode. The second electrode including the metal complex mediator does not include other mediators that would materially affect the basic electrochemical operation of the second electrode. The difference in the redox potentials of the organic mediator at the working electrode versus the metal complex mediator at the counter electrode creates an electrical imbalance that would have been expected to provide poor linearity in the correlation

performance of such a sensor strip. Hence, the linear correlation observed and claimed by Applicants was unexpected.

As previously discussed with regard to independent claim 1, D1 and D2, alone or in combination, cannot make obvious a sensor strip having a first electrode including an electroactive organic molecule and an oxidoreductase and a second electrode including a metal complex mediator, but excluding other mediators that would materially affect the basic electrochemical operation of the second electrode. Neither can these references make obvious a method performed with such a strip where the correlation between the current and the concentration of the analyte is substantially linear from zero to an analyte concentration of about 400 mg/dL. While Applicants' agree that D1 teaches a 35 to 1000 mg/dL correlation between current and analyte concentration (Col. 14, Lines 25-28), such a correlation cannot make the claimed range obvious as the range of D1 was not obtained from a sensor strip having different mediators at the working and counter electrodes (D1 uses ferricyanide at both electrodes). Being from a different device that operates in a different manner, the D1 range cannot make the range of claim 61 obvious.

For these reasons above, the limitations of claim 61 cannot be obvious in view of D1 and D2. As the claims depending directly or indirectly from claim 61 include the limitations of claim 61, these dependent claims also are not obvious in view of D1 and D2.

As previously described in Applicants' November 24, 2010 response, the claim language "prior to use of the sensor strip in an analysis" is not a statement of use as defined under MPEP § 2144. This language was added to explicitly state what was implicit to the claim; that the strip of claims 1 and 30 is the strip as it exists before use in an analysis. Applicants' do not believe this claim language remains at issue in view the Interview and the above response.

Conclusion

The Applicants believe the Examiner's concerns have been addressed to overcome the rejections. Upon review of this amendment and response, Examiner Salzman is respectfully requested to telephone Jonathan M. Blanchard at 312-612-6700 to resolve any outstanding issues as expeditiously as possible so the case may be passed to issue.

Respectfully Submitted,

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Date

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